Natural health products good manufacturing practices pre-inspection package:

Checklist for packagers

Health Canada Santé Canada

Canada

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Trousse de préinspection des bonnes pratiques de fabrication des produits de santé naturels : Liste de vérification pour les emballeurs

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Regulatory Operations and Enforcement

Specifications (section 44, if applicable)

- ☐ In cases where there is a quality agreement in place indicating the packager is responsible for product release:
  - ☐ product specifications for all products packaged at the site
  - ☐ product specifications are approved by the quality assurance person (QAP)
- ☐ For liquid products:
  - ☐ microbiological test results obtained on the finished product after packaging or evidence of microbial controls used to mitigate the risk of contamination during the filling process
    - ☐ a certificate of analysis (CoA) is sufficient if a third-party laboratory conducts the testing

Premises (section 45)

- ☐ A detailed floor plan showing non-production, quarantine and packaging areas
- ☐ Standard operating procedures (SOPs) and associated records for:
  - ☐ prevention of contamination and cross-contamination of natural health products (NHPs)
  - ☐ storage conditions of packaging materials, bulk and finished products
  - ☐ pest control
  - ☐ janitorial duty schedule and cleaning completion
  - ☐ ventilation inspection and maintenance records (as applicable)
  - ☐ restricting access to storage areas for printed materials
  - ☐ water quality testing
  - ☐ facility inspection and maintenance

Equipment (section 46)

- ☐ Preventative maintenance schedule or program for equipment, which includes identification of equipment and instructions on how to maintain it

- ☐ Equipment usage, cleaning and maintenance logs
- ☐ Calibration program and records for equipment that requires it, including proof of the calibration standard or reference being used
- ☐ SOPs for the operation of equipment

Personnel (section 47)

- ☐ SOPs for the appropriate education, training or work experience for all personnel
- ☐ List of qualified QAP designate(s)
- ☐ Records of completed training relating to assigned duties and responsibilities (for example good manufacturing practices (GMP) training) of personnel
- ☐ Employee training schedule or attendance records that demonstrate initial and on-going relevant training
- ☐ Job descriptions that outline roles and responsibilities of positions
- ☐ Résumé or curriculum vitae that show the person meets their job description

Sanitation program (section 48)

- ☐ SOPs and associated records for a sanitation program that includes information on cleaning of premises, packaging and storage areas and equipment, such as:
  - ☐ storage and protection of equipment after cleaning
  - ☐ procedures for destroying and disposing of waste materials and debris
  - ☐ cleaning and sanitizing agents to be used
  - ☐ cleaning frequencies
  - ☐ facility cleaning schedule
  - ☐ cleaning completion
- ☐ SOPs and associated records for a health and hygiene program that includes:
  - ☐ personnel hygiene training
  - ☐ guidance related to personal hygiene

Operations (section 49)

- ☐ SOPs and associated records for:

- transporting, receiving, handling, storing, and distributing packaging materials, bulk or finished products
- packaging NHPs
- sampling records for packaging components
- product disposition, return and disposal
- packaging material specifications, CoAs and release records for all packaging materials
- out-of-specification (OOS) results related to packaging material, including investigations into root causes and resulting corrective and preventive actions
- product complaints and resulting action

- Ensure polymer-based packaging material are acceptable (if used)
- Master production documents and batch records
- Quality agreements with contractors (for example, manufacturers, packagers, labellers, importers, warehouses, test labs, wholesalers, quality assurance consultants) and suppliers
- List of all contract manufacturers, packagers and labellers used domestically and in foreign countries, as applicable

Operations (section 50)

- SOPs and associated records for recalling a NHP and recall reporting
- Each lot of released finished product has distinct identification for traceability (for example, lot number)
- Distribution records for all products
- Signed quality agreement outlining recall responsibilities

Quality assurance (section 51)

- Organizational chart showing independence of QAP's function
- Identification of the QAP and delegate (where applicable)
- QAP's and delegate's (where applicable) résumé, including education

- ☐ QAP's training record demonstrating ongoing and relevant training
- ☐ SOPs and associated records for:
  - ☐ QAP job description that outlines roles and responsibilities, required training, experience and technical knowledge
  - ☐ approval of packaging materials and finished products
  - ☐ releasing packaging materials and finished products (if applicable)
  - ☐ investigation and resolution/corrective actions for complaints, deviations, OOS test results, and returned, rejected and expired products
  - ☐ disposition, distribution and disposal of products
  - ☐ review and approval of methods, procedures and systems used to package NHPs
- ☐ Approved finished product specifications, if applicable
- ☐ Approved finished product release records, if applicable

Records (section 54) and record maintenance (section 58)

- ☐ List of all NHPs packaged at the site
- ☐ A copy of the sanitation program in use at the site
- ☐ Records demonstrating that each lot or batch of the NHP was packaged in accordance with the requirements of Part 3 of the regulations
- ☐ Packaging order
- ☐ Test or evaluation results and release records for packaging material
- ☐ Relevant records are maintained for a period of 1 year following the expiry date of the NHP to which the record relates
- ☐ Records containing sufficient information to enable a recall, which includes product distribution records
- ☐ SOPs for the maintenance of records by packagers, including the following:
  - ☐ change control
  - ☐ record control and retention

- control of electronic records
- use of electronic signatures
- good documentation practices
- document translation
- review and approval of GMP documents
- SOP creation and maintenance

- When an electronic document management system is in place:
  - information that supports the suitability and reliability of the system
  - documentation that outlines the development and maintenance of the system
- When electronic signatures are in use:
  - documentation detailing the development and maintenance of the electronic signature identification system
  - they must be tested and evaluated for security, validity and reliability
- Packaging material specifications
- For packagers of liquid products:
  - documents demonstrating microbial controls to mitigate the risk of contamination during the filling process, or
  - microbiological test results obtained after packaging

Sterile natural health products (section 59) and ophthalmic use (section 60)

- SOPs and associated records for:
  - packaging processes
  - environmental control of particulate and microbial contamination
  - clean room entry and exit process for personnel and materials
  - clean room maintenance
  - laminar flow maintenance
  - product sterilization

- in-process and finished product testing
- QAP and product support staff qualifications and specialized training in microbiology (applies only to staff supervising the sterile packaging)

- Detailed floor plan showing movement of personnel and materials during sterile packaging
- Product-specific process validation for all critical steps of the packaging process, requalification and controls of the sterilization process
- For more information, refer to Annex 1 to the Good manufacturing practices guide – Manufacture of sterile drugs (GUI-0119)